IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant	:	Keneth K. Cyr, et al.		
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Title	:	SYSTEM AND METHOD FOR MANAGEMENT OF CLINICAL SUPPLY OPERATIONS		
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Examiner	:	Jason B. Dunham		
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Commissioner for Patents
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RESPONSE AND REQUEST FOR CONTINUED EXAMINATION

The present communication is submitted in response to the Examiner's remarks in the Final Office Action mailed January 28, 2010 the three-month statutory period for response to which expires on April 28, 2010. A Request for Continued Examination is submitted with the present communication. In response to the Final Office Action, please consider the following:

Proposed Amendments to the Claims are reflected in the Listing of Claims that begins on page 2 of this paper.

Remarks: begin on page 11 of this paper.

AMENDMENTS TO THE CLAIMS

All claims currently pending and under consideration in the present application are shown below. This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (Currently Amended) One or more computer-storage media having ~~A computerized system having a processor and~~ computer-executable instructions embodied thereon for automatically fulfilling orders for clinically related supplies ~~embodied on one or more computer-storage media~~, comprising:

~~an interface to a supply chain engine, the supply chain engine~~ automatically generating ~~at least one~~ orders for clinically related supplies based upon real time supply consumption data derived from documentation of at least one clinical event generated while the clinical event is carried out, the supply consumption data including items used or consumed during the at least one clinical event, wherein the clinical event is carried out at a clinically related site having a plurality of clinical departments; and

~~a fulfillment engine, communicating with the interface to the supply chain engine to receive the at least one order, the fulfillment engine,~~ determining that a first subset of the clinically related supplies specified in the ~~at least one~~ orders are suitable for aggregation because the clinically related supplies are non-time sensitive; ~~and~~

determining that a second subset of the clinically related supplies specified in the orders are not suitable for aggregation because the clinically related supplies are time sensitive;

without user intervention, accumulating a plurality of orders for the clinically related supplies in the first subset for delivery from a vendor before triggering delivery of the clinically related supplies in the first subset from the vendor, wherein the plurality of orders are received from more than one of the plurality of clinical departments; and

without user intervention, triggering delivery of the clinically related supplies in the second subset without aggregation.

2. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility.

3. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the supply consumption data further includes at least one of clinically available quantities of surgical devices, clinically available quantities of pharmaceuticals and clinically available quantities of consumable material.

4. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the ~~supply chain engine generates~~ method further comprises generating the at least one clinical supply order based upon at least one clinical quantity threshold.

5. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the at least one order for clinically related supplies comprises a purchase order.

6. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the supply consumption data further includes supply codes captured in the clinically related site.

7. (Currently Amended) ~~A system~~ The media according to claim 6, wherein the supply codes comprise at least one of optically scanned bar codes, radio frequency identification codes and manually entered codes.

8. (Canceled)

9. (Currently Amended) ~~A system~~ The media according to claim 1 ~~8~~, wherein the clinically related supplies in the first subset are determined to be suitable for aggregation because the clinically related supplies in the first subset are also categorized as non critical.

10. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the at least one order for clinically related supplies is associated with an individual patient supply record.

11. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the clinically related supplies in the first subset are determined to be suitable for aggregation because the clinically related supplies in the first subset are also categorized as receiving a favorable purchase price when ordered in a batch.

12. (Currently Amended) ~~A system~~ The media according to claim 1, wherein the ~~fulfillment engine~~ the method further comprises trigging ~~triggers~~ delivery of the at least one order for clinically related supplies based upon the at least one order for clinically related supplies and upon a set of rules, and wherein the set of rules comprises a set of selectors based at least upon patient condition information, patient demographic information and supply location information.

13. (Canceled)

14. (Canceled)

15. (Currently Amended) A method for automatically fulfilling orders for clinically related supplies, comprising:

tracking, at a computing device, a clinical supply inventory at a clinically related site;

generating a pick ticket including a selection of clinically related supplies for a clinical event;

retrieving the clinically related supplies from storage;

consuming the clinically related supplies during the clinical event;

updating a patient supply record in real time to generate real time supply consumption data indicating the clinically related supplies that were consumed in the clinical event;

automatically generating at least one order for the clinically related supplies based on the real time supply consumption data derived from documentation of the clinical event generated while the clinical event is carried

out, the supply consumption data including items used or consumed during the at least one clinical event at the clinically related site;

determining that a favorable purchase price for at least one of the clinically related supplies may be derived by aggregating orders for the at least one of the clinically related supplies;

determining that the at least one of the clinically related supplies is also non-time sensitive;

upon said determining that the favorable purchase price may be derived and the at least one of the clinically related supplies is non-time sensitive, without human intervention, accumulating additional orders for the at least one of the clinically related supplies prior to triggering delivery; and

triggering delivery of the at least one of the clinically related supplies after accumulating multiple orders for the at least one of the clinically related supplies.

16. (Original) A method according to claim 15, wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility.

17. (Previously Presented) A method according to claim 15, wherein the supply consumption data further includes at least one of clinically available quantities of surgical devices, clinically available quantities of pharmaceuticals and clinically available quantities of consumable material.

18. (Original) A method according to claim 15, wherein the step of automatically generating at least one order comprises a step of generating the at least one clinical supply order based upon at least one clinical quantity threshold.

19. (Original) A method according to claim 15, wherein the at least one order for clinically related supplies comprises a purchase order.

20. (Previously Presented) A method according to claim 15, wherein the supply consumption data comprises supply codes captured in the at least one clinically related site.

21. (Original) A method according to claim 20, wherein the supply codes comprise at least one of optically scanned bar codes, radio frequency identification codes and manually entered codes.

22. (Previously Presented) A method according to claim 15, wherein the at least one order comprises a plurality of orders, further comprising a step of aggregating the orders for clinically related supplies for delivery from a single vendor.

23. (Previously Presented) A method according to claim 22, wherein the orders for clinically related supplies are accumulated for a plurality of clinical departments within the clinically related site.

24. (Original) A method according to claim 15, further comprising a step of associating the at least one order for clinically related supplies with an individual patient supply record.

25. (Original) A method according to claim 15, wherein the triggering of delivery of the at least one order for clinically related supplies comprises triggering delivery based upon the at least one order for clinically related supplies and upon a set of rules.

26. (Original) A method according to claim 25, wherein the set of rules comprises a set of selectors based at least upon patient condition information, patient demographic information and supply location information.

27. (Currently Amended) A method for generating a set of clinically related supplies generated for delivery, method comprising:

automatically generating, at a computing device, at least one order for clinically related supplies based upon real time supply consumption data derived from documentation of at least one clinical event generated while the clinical event is carried out, the supply consumption data including items used and/or consumed during the at least one clinical event at a clinically related site;

determining that a favorable purchase price for at least one of the clinically related supplies may be derived by aggregating orders for the at least one of the clinically related supplies;

upon said determining, without human intervention, accumulating additional orders for the at least one of the clinically related supplies prior to triggering delivery; and

triggering delivery of the at least one of the clinically related supplies based at least upon the at least one order for clinically related supplies.

28. (Previously Presented) The method according to claim 27, wherein the clinically related site comprises at least one of a hospital facility, a research facility and a government facility.

29. (Previously Presented) The method according to claim 27, wherein the supply consumption data further includes at least one of clinically available quantities of surgical devices, clinically available quantities of pharmaceuticals and clinically available quantities of consumable material.

30. (Previously Presented) The method according to claim 27, wherein the step of automatically generating at least one order comprises a step of generating the at least on clinical supply order based upon at least one clinical quantity threshold.

31. (Previously Presented) The method according to claim 27, wherein the at least one order for clinically related supplies comprises a purchase order.

32. (Previously Presented) The method according to claim 27, wherein the supply consumption data further includes supply codes captured in the at least one clinically related site.

33. (Previously Presented) The method according to claim 32, wherein the supply codes comprise at least one of optically scanned bar codes, radio frequency identification codes and manually entered codes.

34. (Previously Presented) The method according to claim 27, wherein the at least one order comprises a plurality of orders, and the method further comprises a step of aggregating the orders for clinically related supplies for delivery from a single vendor.

35. (Previously Presented) The method according to claim 34, wherein the orders for clinically related supplies are aggregated for a plurality of clinical departments within the clinical site.

36. (Previously Presented) The method according to claim 27, wherein the method further comprises a step of associating the at least one order for clinically related supplies with an individual patient supply record.

37. (Previously Presented) The method according to claim 27, wherein the triggering of delivery of the at least one order for clinically related supplies comprises triggering delivery based upon the at least one order for clinically related supplies and upon a set of rules.

38. (Previously Presented) The method according to claim 37, wherein the set of rules comprises a set of selectors based at least upon patient condition information, patient demographic information and supply location information.

REMARKS

The Final Office Action mailed January 28, 2010, has been received and reviewed. Prior to the present communication, claims 1-7 and 9-38 were pending in the subject application. All claims stand rejected. Each of claims 1–7, 9-12, 15, and 27 has been amended herein, while claims 13 and 14 have been cancelled. As such, claims 1-7, 9-12, and 15-38 remain pending. It is submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Claim Objections

Claim 9 was objected to because it was dependent upon canceled claim 8. Claim 9 has been amended to be dependent upon claim 1. Accordingly, Applicants ask the Office to withdraw the objection to claim 9.

Rejections based on 35 U.S.C. § 103

A.) Applicable Authority

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in *Graham v. John Deere* counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966).

To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in Graham and to provide some "articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.,* 127 S. Ct. 1727 at 1741, 82 USPQ2d at 1396 (quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) with approval)." *See also* MPEP § 2142. "[R]ejections on obviousness cannot be sustained with mere conclusory statements." *Id.* Thus, in order to establish a prima facie case of obviousness the Office must provide "a clear articulation of the reason(s) why the claimed invention would have been obvious" based on factual findings made while conducting the Graham factual inquires. *See* MPEP § 2143. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. *Id.*

B.) Obviousness rejection based upon U.S. Patent No. 5,682,728 to DeBusk in view of U.S. Publication No. 2001/0016821 to DeBusk '821

Claims 1-7 and 9-38 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,682,728 to DeBusk (hereinafter DeBusk) in view of U.S. Patent No. 2001/0016821 to DeBusk (hereinafter DeBusk '821). As explained in more detail below, several elements of the claimed invention are not rendered obvious by the combination of references. Accordingly, Applicants respectfully traverse the rejection, as hereinafter set forth.

As presently amended, the claim 1 describes one or more computer-storage media having computer-executable instructions for automatically fulfilling orders for clinically related supplies. The method includes automatically generating orders for clinically related supplies based upon real time supply consumption data derived from documentation of at least one clinical event generated while the clinical event is carried out, the supply consumption data including items used or consumed during the at least one clinical event. The clinical event is

carried out at a clinically related site having a plurality of clinical departments. The method includes determining that a first subset of the clinically related supplies specified in the orders are suitable for aggregation because the clinically related supplies are non-time sensitive. The method also includes determining that a second subset of the clinically related supplies specified in the orders are not suitable for aggregation because the clinically related supplies are time sensitive. The method also includes, without user intervention, accumulating a plurality of orders for the clinically related supplies in the first subset for delivery from a vendor before triggering delivery of the clinically related supplies in the first subset from the vendor. The plurality of orders are received from more than one of the plurality of clinical departments. The method also includes without user intervention, triggering delivery of the clinically related supplies in the second subset without aggregation.

In contrast, the DeBusk reference, describes the management of consumable medical supplies by creating bills of material associated with care events within a clinical pathway. *See DeBusk reference* at col. 2, l. 29-37. A bill of materials representing those medical supplies "to be used" for a scheduled care event is generated and those supplies are placed into supply bundles at a number of locations and then delivered in bundled form to the end-user. *See id.* at col. 2, l. 50 to col. 3, l. 2; and col. 3, l. 34. The DeBusk reference also discloses anticipating supply usage based upon historical records relating to the frequency of occurrence of given care events at a particular facility and/or aggregated facility usage of common medical supplies over time. *See id.* at col. 2, l. 59 to col. 6, l.13. The DeBusk '821 reference describes improvements to the system described in the DeBusk reference. *See* DeBusk '821 reference.

At least two aspects of claim 1 are not obvious in view of the cited references. Specifically, neither the "accumulation" of orders nor the "generation" of orders based on "real time" supply data are obvious in review of the DeBusk reference and the DeBusk '821 reference.

The method in claim 1 accumulates "a plurality of orders ... before triggering delivery of the clinically related supplies." At issue is the criteria used to accumulate the orders. In claim 1, orders in a first subset are determined to be "suitable for aggregation because the clinically related supplies are non-time sensitive." A second subset of orders is determined to be time sensitive and are not accumulated. Thus, the criteria for accumulation of orders is whether the orders are time sensitive. In contrast, the DeBusk reference groups clinical supplies according to a procedure. Clinical items needed to perform a procedure are bundled together. *See* DeBusk reference col. 3, ll. 40-45. The DeBusk '821 reference also bundles clinical supplies together based on procedure. *See* DeBusk '821 reference abstract. Thus, the DeBusk reference accumulates orders based on procedure, not time sensitiveness. The Office has not provided a rational reason why accumulating orders based on procedures makes it obvious to accumulate orders based on whether or not they are non-time sensitive.

Before the orders can be accumulated they must first be generated. The orders in claim 1 are automatically generated based upon "real time supply consumption data derived from documentation of at least one clinical event generated while the clinical event is carried out." Real time supply consumption data is the key information used to generate the order. The DeBusk '821 reference describes real time supply consumption data. *See* DeBusk '821 reference [0120]. But, the real time supply data is not used to generate an order. Rather, an order for supplies is generated when a patient schedules a procedure. *See* DeBusk reference '821 [0090]. The real time supply data is used to anticipate the number clinical supplies needed over a period

of time, not generate orders directly. *See* DeBusk reference '821 abstract. At issue is how the DeBusk references uses the real-time supply data. Merely describing real time supply data without using it to automatically generate orders does not render this feature of claim 1 obvious.

The DeBusk reference describes the management and procurement of supply bundles containing medical supplies "intended for use" in a future care event. *See DeBusk reference* at col. 5, l. 22-45. The number of bundles ordered during the year may be based on historical usage data that shows how many bundles are typically used during a period of time. *See id.* at col. 2, l. 59 to col. 6, l.13. In contrast, claim 1 describes automatically generating orders to replenish used supplies (i.e., items used and/or consumed during a clinical event) by basing the order on real time supply consumption data. Basing orders on historical usage data, as described in the DeBusk reference, is not the same as automatically generating orders based on real time consumption data. Thus, the DeBusk reference does not describe "automatically generating at least one order based on real time supply consumption data."

Thus, Applicants respectfully suggest that the Office has not carried its burden of establishing a *prima facie* case of obviousness because the combinations of references do not describe all elements of independent claims 1. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection thereof. Further, each of claims 2-7 and 9-14 depends, either directly or indirectly, from independent claim 1 and defines further patentable features. Accordingly, each of these claims is allowable at least by virtue of its dependence from allowable claim 1. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1-7 and 9-14 is respectfully requested.

As presently amended, claim 15 recites a method for automatically fulfilling orders for clinically related supplies. The method includes tracking, at a computing device, a

clinical supply inventory at a clinically related site. The method also includes generating a pick ticket including a selection of clinically related supplies for a clinical event. The method further includes retrieving the clinically related supplies from storage and consuming the clinically related supplies during the clinical event. The method further includes updating a patient supply record in real time to generate real time supply consumption data indicating the clinically related supplies that were consumed in the clinical event. The method also includes automatically generating at least one order for the clinically related supplies based on the real time supply consumption data derived from documentation of the clinical event generated while the clinical event is carried out, the supply consumption data including items used or consumed during the at least one clinical event at the clinically related site. The method also includes determining that a favorable purchase price for at least one of the clinically related supplies may be derived by aggregating orders for the at least one of the clinically related supplies. The method also includes determining that the at least one of the clinically related supplies is non-time sensitive. The method includes, upon said determining that the favorable purchase price may be derived and the at lest one of the clinically related supplies is non-time sensitive, without human intervention, accumulating additional orders for the at least one of the clinically related supplies prior to triggering delivery. The method also includes triggering delivery of the at least one of the clinically related supplies after accumulating multiple orders for the at least one of the clinically related supplies.

Applicants respectfully submit that the combination of references fails to describe "upon said determining that the favorable purchase price may be derived and the at lest one of the clinically related supplies is non-time sensitive, without human intervention, accumulating additional orders for the at least one of the clinically related supplies prior to triggering

delivery." The DeBusk reference and the DeBusk '821 reference bundle supplies based on procedures. They do not describe accumulating supplies that are non-time sensitive and upon determining that the favorable purchase price may be derived by accumulating orders. Further, for reasons similar to those given with reference to claim 1, the combination of references do not describe "generating at least one order for the clinically related supplies based on the real time supply consumption data derived from documentation."

Thus, Applicants respectfully suggest that the Office has not carried its burden of establishing a *prima facie* case of obviousness because the combinations of references do not describe all elements of independent claims 15. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection thereof. Further, each of claims 16-26 depends, either directly or indirectly, from independent claim 15 and defines further patentable features. Accordingly, each of these claims is allowable at least by virtue of its dependence from allowable claim 15. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 15-26 is respectfully requested.

As presently amended, claim 27 recites a method for generating a set of clinically related supplies generated for delivery. The method includes automatically generating, at a computing device, at least one order for clinically related supplies based upon real time supply consumption data derived from documentation of at least one clinical event generated while the clinical event is carried out, the supply consumption data including items used and/or consumed during the at least one clinical event at a clinically related site. The method also includes determining that a favorable purchase price for at least one of the clinically related supplies may be derived by aggregating orders for the at least one of the clinically related supplies. The method further includes, upon said determining, without human intervention, accumulating

additional orders for the at least one of the clinically related supplies prior to triggering delivery. The method also includes triggering delivery of the at least one of the clinically related supplies based at least upon the at least one order for clinically related supplies.

Applicants respectfully submit that the combination of references fails to describe "upon said determining" that a favorable purchase price for at least one of the clinically related supplies may be derived by aggregating orders for the at least one of the clinically related supplies, "without human intervention, accumulating additional orders for the at least one of the clinically related supplies prior to triggering delivery." The DeBusk reference and the DeBusk '821 reference bundle supplies based on procedures. They do not describe accumulating supplies upon determining that the favorable purchase price may be derived by accumulating orders. Further, for reasons similar to those given with reference to claim 1, the combination of references do not describe "generating, at a computing device, at least one order for clinically related supplies based upon real time supply consumption data."

Thus, Applicants respectfully suggest that the Office has not carried its burden of establishing a *prima facie* case of obviousness because the combinations of references do not describe all elements of independent claims 27. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection thereof. Further, each of claims 28-38 depends, either directly or indirectly, from independent claim 27 and defines further patentable features. Accordingly, each of these claims is allowable at least by virtue of its dependence from allowable claim 27. As such, withdrawal of the 35 U.S.C. § 103(a) rejection of claims 27-38 is respectfully requested.

CONCLUSION

For at least the reasons stated above, each of claims 1-7, 9-12, and 15-38 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.474-6550 or via email at johoward@shb.com (such communication via email is herein expressly granted)—to resolve the same prior to issuing a subsequent action.

The fee for an RCE is submitted herewith. It is believed that no additional fee is due in conjunction with the present communication. However, if this belief is in error, the Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.111423.

Respectfully submitted,

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